K121654

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SEP 5 2012

510(k) Summary

(As required by 21 CFR 807.92)

Type of 510(k): **Special 510(k)**

Submitted By:
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Prepared Date: May 25, 2012

Device Name:
Trade name: **AUTO-CHEK Blood Glucose Monitoring System**
Common Name: Glucose Test System

Regulatory Information:

1) Regulation section:	21 CFR 862.1345 Glucose Test System, 21 CFR 862.1660, Quality control material
2) Classification:	Class II, Class I
3) Product Code:	CGA - glucose oxidase, glucose NBW - system, test, blood glucose, over the counter JJX - Quality control material
4) Panel:	Clinical Chemistry (75)

Intended Use:

The AUTO-CHEK Blood Glucose Monitoring System is intended for the quantitative measurement of glucose in fresh capillary whole blood samples drawn from the fingertips and alternative sites such as the forearm, palm, thigh, and calf. Alternative site testing should be used only during steady-state blood glucose conditions. The AUTO-CHEK Blood Glucose Monitoring System is intended for self testing outside the body (*in vitro*) by people with diabetes at home as an aid to monitor the effectiveness of diabetes control. The system is intended to be used by a single person and should not be shared. It is not intended for use on neonates and is not for the diagnosis or screening of diabetes.

The AUTO-CHEK Blood Glucose Test Strips are for use with the AUTO-CHEK Blood Glucose Meter to quantitatively measure glucose in fresh capillary whole blood samples drawn from the fingertips and alternative sites.

The AUTO-CHEK Control Solutions are for use with the AUTO-CHEK Meter and AUTO-CHEK Test Strips to check that the meter and the test strips are working together properly and that the test is performing correctly.

Device Description:

The AUTO-CHEK Blood Glucose Monitoring System (BGMS) measures the glucose level in whole blood samples using a small electrical current generated in the test strips. The system consists of the followings: the AUTO-CHEK Meter, AUTO-CHEK Test Strips, AUTO-CHEK Control Solutions with two different glucose concentrations ("Control A" and "Control B" ranges, sold separately), a Lancing Device, Lancets, a User's manual, and a Logbook.

Substantial Equivalence Information:

1) Predicate Device Name: **COOL Blood Glucose Monitoring System**

2) Predicate 510(k) Number: k103396

2) Comparison with Predicate Device:

The modified AUTO-CHEK BGMS has the following features that are identical to the predicate device:

- Intended use
- Measurement principle
- Fundamental scientific technology
- Technical specifications
- Operating ranges

The modifications that was made on the AUTO-CHEK BGMS compared to COOL BGMS are:

- **The shape of meter's housing**
- **The electric connector pattern of the test strip**

Type of Test: Quantitative, Amperometric method, Glucose oxidase *(Aspergillus sp.)*

Test Principle: The reagent on the test strip produces a small electrical current using glucose as a substrate in the blood sample. The meter converts electrical current to glucose concentration.

Technological Characteristics: The AUTO-CHEK BGMS has the same fundamental scientific technology as the predicate device.

Assessment of Performance Characteristics: When compared with the predicate device, the basic features of the candidate device, the intended use, measurement principle, fundamental scientific technology, technical specifications, and operating ranges, are all the same. The only differences are the shape of meter's housing and electric connector pattern of the test strip. The validations were conducted in order to verify that the modified electric connector pattern has not caused any adverse effects on the safety and effectiveness of the candidate device. The test results showed that the candidate device operated effectively, accurately, and safely.

Summary of Pre-cleaning and Disinfection: Disinfection studies were performed on the AUTO-CHEK meter and lancing device by an outside commercial testing service to evaluate effectiveness of disinfectant, CLOROX GERMICIDAL Wipes (EPA Reg. No: 67619-12), in preventing the spread of blood-borne pathogens, using hepatitis B virus

(HBV). The results demonstrated complete inactivation of live virus inoculated on the materials of the meter and lancing device. We have also demonstrated that 260 each of pre-cleaning and disinfection cycles with the same disinfectant designed to simulate 5 years of use has not affected either the performance of the meter and the lancing device or the external materials of the meter and lancing device demonstrating the robustness of the meter and lancing device.

Conclusion: **Based on the validation results, the candidate device, AUTO-CHEK BGMS, is substantially equivalent to the predicate device. Further, the AUTO-CHEK BGMS has met the performance, safety, and effectiveness of the device for its intended use.**

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration

10903 New Hampshire Avenue
Silver Spring, MD 20993

I-SENS, Inc.
c/o Hyun Joon Oh
Division Manager, Quality Assurance
465-6 Wolgye-Dong, Nowon-GU
SEOUL, Republic of Korea 139-845

SEP 5 2012

Re: k121654
Trade Name: AUTO-CHEK Blood Glucose Monitoring System
Regulation Number: 21 CFR §862.1345
Regulation Name: Glucose test system
Regulatory Class: Class II
Product Codes: CGA, NBW, JJX
Dated: August 1, 2012
Received: August 6, 2012

Dear Dr. Hyun Joon Oh:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (301) 796-5760. For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance...

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-5680 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm

Sincerely yours,

Courtney H. Lias, Ph.D.
Director
Division of Chemistry and Toxicology Devices
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Indications for Use Form

510(k) Number (if known): K121654

Device Name: AUTO-CHEK Blood Glucose Monitoring System

Indications for Use:

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Prescription Use _____ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use X (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety

510(k) K121654